UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,531	12/19/2000	John Craig Smith	PM 275901	2393

26161 7590 01/09/2003

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER
EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 01/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/720,531	SMITH ET AL.	
	Examiner	Art Unit	
	Juliet C Einsmann	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 3, and 8, drawn to methods of diagnosing single nucleotide polymorphisms and methods of treatment subsequent to such diagnosis.

Group II, claim(s) 4, 5, 6, 7, and 11, drawn to nucleic acids, primers, probes, computer readable media, and kits containing the same.

Group III, claim(s) 9, drawn to methods for preparing medicaments.

Group IV, claim(s) 10, drawn to a pharmaceutical pack.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The relationship between groups I and II are that they are nucleic acids containing polymorphisms and methods for detecting polymorphisms in nucleic acids. Claim 4 is broadly drawn so as to encompass any nucleic acid that comprises a human CCR2 gene comprising a T at position 2385 and/or an A at position 2649. Such a nucleic acid is provided in the prior art

(see JP 09238688 A, see nucleotides 780 and 1044). Thus, such nucleic acids cannot be considered a special technical feature that joins groups I and II, since the nucleic acids of claim 4 do not provide a special technical feature over the prior art.

The methods recited in groups I and III are not joined by a special technical feature because they are not directed at solving the same problem. One is directed towards the diagnosis of a polymorphism or treatment of disease, while the other is directed towards the making of a medicament. 37 CFR 1.475 states that "If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other category related thereto will be considered as the main invention of the claims." The methods of claim 9 are directed towards the preparation of a medicament and would thus require the steps of preparing the medicament that are not mentioned or required by the other claims. Further, these methods do not recite or require the products of groups II or IV.

The pharmaceutical packs of claim 10 have are not joined to any of the other products of group II claims because they have a different structure from the nucleic acids and have a different function from the nucleic acids in that the nucleic acids encode polypeptides while the pharmaceutical packs of claim 10 contain drugs that are CCR-2 antagonists.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Each of the single nucleotide polymorphisms as recited, for example, in claim 1. there are thirteen in total.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Alternatively, Applicant may elect a single group of polymorphisms for examination with the elected group, in light of the fact that the claims each contain language that refers to "one or more" of the recited polymorphisms.

Portions of MPEP 803.04 are repeated herein for Applicant's convenience.

> "Examples of typical nucleotide sequence claims impacted by the partial waiver of 37 CFR 1.141 et seq. (and the partial waiver of 37 CFR 1.475 and 1.499 et seq., see MPEP § 1850) include...C) a combination of DNA fragments, said combination containing at least thirty different DNA fragments selected from SEQ ID Nos. 1-1,000...Applications containing only composition claims reciting different combinations of individual nucleotide sequences, such as set forth in example (C), will be subject to a restriction requirement. Applicants will be required to select one combination for examination. ...The identification of any allowable sequence(s) will cause all combinations containing the allowed sequence(s) to be allowed."

The claims differ from those discussed in MPEP 803.04 in a number of significant ways, one being that the sequences discussed in MPEP 803.04 are isolated DNA fragments whereas the instant claims are drawn to methods and products which utilize and comprise DNA polymorphisms. Upon the finding of an allowable combination, combinations which comprise the allowable combination will also be rejoined and allowed.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Each of these species is to a separate single nucleotide polymorphism in the human CCR-2 gene, and thus share this feature. However, this is not a special technical feature that links the claims in view of at least the prior art provided by Smith et al. (Science, 1997, Vol. 277, pages 959-965) who disclose a polymorphism in the CCR-2 gene (see abstract). Thus, the fact that polymorphisms are disclosed in the CCR-2 gene is not a special technical feature in view of the prior art.

Furthermore, Section (f)(i)(B)(1) of Annex B of the Administrative Instructions requires that all alternatives of a Markush group have a common structure. In the instant case, the first claimed invention is a method claim which recites the diagnosis of thirteen different polymorphisms in a Markush type format. Each of the separate polymorphism disclosed in the claims have a common structure in that they all require within the CCR-2 gene, however, that common structure is not a contribution over the prior art. The CCR-2 gene was known in the art at the time the invention was made, as were methods for diagnosing polymorphisms in the gene (EMBL ACCESSIONS U80924 and U95626 and Smith et al). Thus, the common structure which links the species does not provide a "special technical feature" over the prior art.

Section (f)(i)(A) of Annex B of the Administrative Instructions requires that all alternatives of a Markush group have a common property or activity in order for Unity of Invention to be present. Although the methods of claims 1-3 share a common structure in that they all require analysis of the CCR-2 gene for polymorphisms, the set of methods is not regarded as being of a similar nature because all of the alternatives do not share a common property or activity. Each method is directed at looking for a distinct polymorphism whose structure is not the same as any of the alternative polymorphisms. Further, the set of

polymorphisms are not joined by a common activity. While the particular effect of each of these polymorphisms is unknown, if any change in expression results from the presence or a particular allele in these polymorphic sites, that effect would be specific to the particular polymorphism, and not a general function or effect shared by all thirteen individual polymorphisms. Thus, each of the methods or products which recite the individual polymorphisms are not joined by a common property or activity, and separation of these groups is proper under the governing PCT rules. This reasoning applies to each of the different groups of method claims provided in the claims.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C. Einsmann
Examiner
Art Unit 1634

January 6, 2003

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600